Docket No.: BSX-228
(10207709)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Peter J. SHANK *et al.*

Confirmation No. 4334

Application/Control No.: 10/720,176

Group Art Unit: 3738

Filed: November 23, 2003

Examiner: David A. Izquierdo

For: COMPOSITE STENT WITH INNER AND OUTER STENT ELEMENTS AND METHOD OF USING THE SAME

APPEAL BRIEF
(37 CFR § 41.37)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Brief is filed pursuant to a March 29, 2006 Notice of Appeal and in accordance with 37 C.F.R. § 41.37. A Pre-Appeal Brief Request for Review was filed on March 29, 2007. A Notice of Panel Decision was mailed on May 18, 2007, reporting that the application "remains under appeal."

Authorization is given to charge any necessary fees to our Deposit Account No. 50-0624 as required under 37 C.F.R. § 41.20(b)(2) for filing this Brief, and any required petition with fee payment for extension of time.

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I. REAL PARTY IN INTEREST

The real party in interest is Scimed Life Systems, Inc., the assignee of record, which is owned entirely by Boston Scientific Corporation.

II. RELATED APPEALS AND INTERFERENCES

There are no other prior or pending appeals or interferences that are related to or will directly affect or be directly affected by or have a bearing on the Board's decision in this pending appeal.

III. STATUS OF CLAIMS

Currently pending claims 2, 3, 7, 22-24 and 28-35 stand rejected and are on appeal. Claims 1, 4-6, 8-21 and 25-37 have been withdrawn from consideration but not cancelled. No claims have been allowed.

IV. STATUS OF AMENDMENTS

No amendment has been submitted for entry subsequent to the mailing of the November 29, 2006 final Office action. All prior submitted amendments have been entered.

V. SUMMARY OF CLAIMED SUBJECT MATTER

There are five independent claims: 23, 28, 29, 30 and 33. There are nine dependent claims: 24 (depends from 23); 2, 3, 7 and 22 (depend from 28); 31 and 32 (depend from 30); and 34, 35 (depend from 33).

Independent apparatus claim 30 covers a stent that is a composite of the claimed combination of a first stent and a second stent. The claimed composite structure includes the second stent being configured to assist the first stent in retaining a position within a body lumen.

Independent apparatus claim 23 is nearly identical to claim 30 except for limitations covering a composite stent that is a combination of a bioabsorbable stent and a self-expanding metal stent (SEMS) releasably engageable within the bioabsorbable stent. In covering a composite stent structure, independent apparatus claim 28 claims an outer stent limited to being a bioabsorbable stent that has open opposite ends, and also claims an inner stent limited to being a self-expending metal stent that has open opposite ends.

Independent method claim 33 claims a method of treatment that includes inserting a composite stent structure into a body lumen. The composite stent structure is recited as including an inner stent within an outer stent. The claimed treatment method further includes expanding the inner stent to cause the outer stent to be positioned in contact with an inner wall of the body lumen. Indepent method claim 29 is nearly identical to claim 33, except for the added proviso for allowing normal functioning of the body lumen by transporting a bodily substance through a composite stent that has an inner stent made of self-expanding metal and an outer stent made of a bioabsorbable material.

The composite stent apparatus specifically recited in independent claim 30 comprises:

> a first stent (Abstract; Paragraphs 0016, 0021, 0022, 0028, 0029, 0030, 0038, 0051, 0052 and 0053; Figures 3, 4 and 5, reference characters 301, 302, 401, 402, 502 and 503); and
>
> a second stent engageable with said first stent to form a composite structure insertable within a body lumen, said second stent configured to assist said first stent in retaining a position of the first stent within the body lumen (Abstract; Paragraphs 0016, 0021, 0022, 0028, 0029, 0030, 0038, 0051, 0052 and 0053; Figures 3, 4 and 5, reference characters 301, 302, 401, 402, 502, 503 and 505).

Whereas, independent apparatus claim 23 recites a composite stent comprising:

> a bioabsorbable stent (Abstract; Paragraphs 0016, 0021, 0022, 0028, 0029, 0030, 0038, 0051, 0052 and 0053; Figures 3, 4 and 5, reference characters 301, 302, 401, 402, 502 and 503); and
>
> a self expanding metal stent releasably engageable within said bioabsorbable stent for insertion within a body lumen as a unit, said self-expanding metal stent biased to position said bioabsorbable stent into engagement with the body lumen (Abstract; Paragraphs 0016, 0021, 0022, 0028, 0029, 0030, 0038, 0051, 0052 and 0053; Figures 3, 4 and 5, reference characters 301, 302, 401, 402, 502, 503 and 505).

Claim 28, the third independent apparatus claim, recites a composite stent comprising:

> an outer stent, said outer stent bring a bioabsorbable stent, and said outer stent being open at opposite ends and having an outer surface engageable with an inner surface of a body lumen (Abstract; Paragraphs 0016, 0020, 0021, 0022, 0028, 0029, 0030, 0038, 0051, 0052, and 0053; Figures 3, 4 and 5, reference characters 301, 302, 401, 402, 502 and 503); and
>
> an inner stent, said inner stent being a self-expanding metal stent, and said inner stent being open at opposite ends, said inner stent engageable with said outer stent to form a composite structure insertable within the body lumen, said inner stent configured to assist said outer stent in retaining a position of the outer stent within the body lumen (Abstract; Paragraphs 0016, 0020, 0021, 0022, 0028, 0029, 0030, 0038, 0051, 0052 and 0053; Figures 3, 4 and 5, reference characters 301, 302, 401, 402, 502, 503 and 505).

Each of independent method claims 29 and 33 recite:

> inserting a composite stent structure into a body lumen, said composite stent structure including an inner stent being within an outer stent (Abstract; Paragraphs 0016, 0017, 0021, 0022, 0028, 0029, 0030, 0038, 0051, 0052 and 0053; Figures 3, 4 and 5, reference characters 301, 302, 401, 402, 502, 503 and 505); and,
>
> expanding said inner stent to cause said outer stent to be positioned into contact with an inner wall of the body lumen (Abstract; Paragraphs 0016, 0017, 0021, 0022, 0028, 0029, 0030, 0038, 0051, 0052 and 0053; Figures 3, 4 and 5, reference characters 301, 302, 401, 402, 502, 503 and 505).

Method independent claim 29, in addition to reciting use of a composite inner and outer stent sturcute, further recites:

> inserting a composite stent structure into a body lumen, said composite stent structure including an inner stent being made of a self-expanding metal, said inner stent being within an outer stent, said outer stent being made of a bioabsorbable material (Abstract; Paragraphs 0016, 0017, 0021, 0022, 0028, 0029, 0030, 0038, 0051, 0052 and 0053; Figures 3, 4 and 5, reference characters 301, 302, 401, 402, 502, 503 and 505);
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> * * *
>
> allowing for normal functioning of the body lumen by transporting a bodily substance through said composite stent structure (Paragraph 0023).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether apparatus claims 2, 3, 7, 22-24, 28 and 30-32, and method claims 29 and 33-35 are anticipated by U.S. Patent No. 6,656,216 (hereinafter Hossainy *et al.*).

VII. ARGUMENT

A. Applicants' Invention

Independent apparatus claims 23, 28 and 30 claim a stent device. For example, independent claim 30 claims a combination of an outer stent with an inner stent to form a composite stent. The inner stent being expandable to assist the outer stent in retaining a position of the composite stent within a body lumen. Independent claims 23 and 28 are nearly identical to claim 30, except for: (i) claim 23 reciting a combination of a bioabsorbable stent with a self-expanding metal stent as being releasably engageable within the bioabsorbable stent; and (ii) claim 28 reciting that the outer stent is a bioabsorbable stent, the inner stent is a self-expanding stent and both stents are open at opposite ends. See section V, *supra*.

Independent method claims 29 and 33 claim a method for treatment using a composite stent inserted into and expanded in a body lumen. The claim 33 claimed composite stent is a combination of an inner stent and an outer stent, and the claim 29 claimed composite stent has the inner stent as being made of a self-expanding metal and the outer stent as being made of bioabsorbable material. Further, claim 29 claims allowing normal functioning of the body lumen by transporting a bodily substance through the inserted and expanded composite stent. See section V, *supra*.

With respect to what is meant by claimed stents, it is explained in the specification:

> Medical prostheses frequently referred to as stents are well known and commercially available. These devices are used within body vessels of humans for a variety of medical applications. Examples

> include intravascular stents for treating narrowing or contraction of body lumens (stenoses), stents for maintaining openings in the urinary biliary, tracheobronchial, esophageal, and renal tracts, and vena cava filters.... (Paragraph 0021).

Also explained in the application is that a stent can be delivered into a position at a treatment site in a compressed state. If the compressed stent is self-expanding, it can be released to allow expansion of the stent within the body vessel or lumen. Alternatively, a balloon, as is explained in the specification, can be used for expanding a stent that is positioned within a body vessel or lumen. (Paragraph 0003)

Specifically, some stents can be made of self-expandable materials such as spring metals and others can be made of bioabsorbable materials that can be broken down by the body and absorbed or passed from the body after some period of time when the stent no longer is needed. (Paragraphs 0004 and 0005)

This dichotomy in material properties used for making stents along with the requirement for expanding stents is recognized and addressed for the disclosed and claimed composite stent:

> The present invention is directed to a composite stent having more than one distinct and separable elements or members – for example an outer stent element (or outer element) and an inner stent element (or inner element). ...The outer element may be, or example, a bioabsorbable stent typically constructed of a relatively non-resilient material such that the outer bioabsorbable stent may not be self-expanding and subject to migration within the lumens over time. In contrast, the inner element may be, for example, and without limitation, a removable self-expanding metal stent (SEMS) used to urge and maintain the position of the outer element in the body lumen. ...(Application Paragraph 0016)

Additionally explained in the specification is use of the claimed composite stent for a treatment method for inserting a combined inner stent and an outer stent into a body lumen and

expansion of the inner stent to cause the outer stent to be positioned in contact with an inner wall of the body lumen. This treatment method further is explained to include "allowing for normal functioning of the body lumen by transporting a bodily substance through the composite stent structure." (Paragraph 0023)

B. The Rejection

The appealed claims are rejected as anticipated over Hossainy *et al.*, because the Examiner alleges:

> Hossainy et al. discloses a composite stent comprised of an outer stent (209) and an inner stent (100) wherein the outer stent is comprised of a bioabsorbable material (col. 4, lines 1-30) and exerts a radial force in an outward direction (col. 3, lines 44-56) and the inner stent is comprised of a metallic material (col. 2, lines 50-65) and also provides a radially outward force (col. 2, line 60-col. 3, line 10). (November 29, 2006 Final Office Action, p. 2)

In the February 13, 2007 Advisory Action the Examiner further alleges:

> Although Applicant has argued that the outer band (209) of the Hossainy reference cannot be characterized as a stent, the outer band is comprised of the same material, and more importantly anticipates the claimed structure of the invention. Applicant's arguments are based on limitations imposed within the Specification and Drawings, not the claim language. Examiner maintains that the bands of Hossainy et al. can be characterized as outer stents and therefore anticipate the outer stent of the claimed invention. (Advisory Action, p. 2)

C. Hossainy et al. Does Not Anticipate Apparatus Claims 2, 3, 7, 22-24, and 30-32 or Method Claims 29 and 33-35

1. Hossainy et al. Does Not Disclose or Suggest "A Second Stent Engageable With [a] First Stent To Form a Composite Structure" as Required By Claims 2, 3, 7, 22-24, 28 and 30-32.

Limitations recited in independent apparatus claim 23 include a composite stent comprising "a bioabsorbable stent; and a self-expanding metal stent releasably engageable

within said bioabsorbable stent...." Independent apparatus claim 28 also recites a composite stent comprising a pair of stents, i.e., "an outer stent...being a bioabsorbable stent...and an inner stent...engageable with said outer stent...." Most broadly recited is independent apparatus claim 30 claimed composite stent comprising: "a first stent; and a second stent engageable with said first stent to form a composite structure...." These three apparatus claims are the anticipation rejected independent claims.

During prosecution, the interpretation of recited limitations is to be made by the Office using a standard that directs that claims be given their broadest reasonable construction "in light of the specification as it would be interpreted by one of ordinary skill in the art."[1] This direction for prosecution by the Office further is set out in the Code of Federal Regulations that directs "...claims must conform to the invention as set forth in the remainder of the specification and the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description."[2]

On turning to the filed specification, it explicitly and consistently is found that the claimed stent structure is disclosed as being a support device for body orifices, cavities, etc. It further explicitly and consistently is found that the claimed stent structure also can be compressed for insertion into such orifices, cavities, etc. prior to expansion into a support device. See section VII A., *supra*.

Medical prostheses frequently referred to as stents are well known and commercially available. These devices are used within body vessels of humans for a variety of medical

[1] *In re Am. Acad. Of Sci. Tech. Ctr,*. 367 F. 3d 1359, 1364 (Fed Cir. 2004)
[2] 37 CFR § 1.75 (d)(1).

applications. Examples include intravascular stents for treating narrowing or contraction of body lumens (stenoses), stents for maintaining openings in the urinary biliary, tracheobronchial, esophageal, and renal tracts, and vena cava filters. (Specification, Paragraph 0002)

Nowhere in the specification is it disclosed or suggested that claimed stents – whether inner, outer or composite – are any other type of structural devices than a body lumen or vessel support device that both can be compressed and expanded from a collapsed configuration.

The Examiner asserts that "Hossainy et al. discloses a composite stent comprised of an outer stent (209) and an inner stent (100) wherein the outer stent is comprised of a bioabsorbable material (col. 4, lines 1-30) and exerts a radial force in an outward direction (col. 3, lines 44-56) and the inner stent is comprised of a metallic material (col. 2, lines 50-65) and also provides a radially outward force (col. 2, lines 60-col. 3, line 10)" (Final Action, Section 4). These conclusions are continued in the Advisory Action: "Examiner maintains that the bands of Hossainy et al. can be characterized as outer stents and therefore anticipate the outer stents of the claimed invention." Further stated in the Advisory Action is that the Hossainy *et al.* "outer band is comprised of the same material, and more importantly anticipates the claimed structure of the invention." No reason is provided in the Advisory Action as support for why the Hossainy *et al.* "outer band...anticipates the claimed structure" other than the Examiner's characterization of the bands as being stents, and that the Hossainy *et al.* bands are "made of the same material."

Despite these assertions by the Examiner, Hossainy *et al.* nowhere discloses or suggests any composite stent including *both* an inner stent and also an outer stent where both stents are structural support devices for body orifices, cavities, etc. that both can be compressed and expanded from a collapsed configuration.

Hossainy *et al.* disclose three embodiments for their so-called "composite stent." Two of these embodiments include a single stent (100 or 300, see Figs. 1-3) having either "regioselective material forming bands 209... applied to the stent 200 [sic] while the stent 200 [sic] is a compressed position" (see Fig. 2; col. 3, lines 20-22) or "a plurality of strips 302... spaced circumferentially around the stent 300" (see Fig. 3, col. 4, lines 50-52). The third embodiment has "an expandable structural frame, which may be formed of metal, polymer, or composite stents or wires" (Col. 2, lines 50-52; see Fig. 1) This third embodiment has not been asserted as anticipating claimed subject matter because it does not.

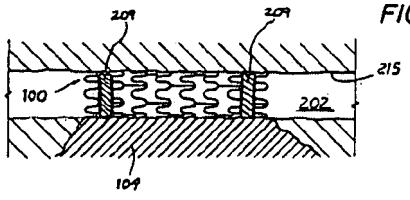

FIG. 2

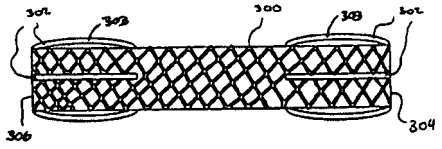

FIG. 3

Hossainy *et al.* nowhere disclose or infer that either bands 209 or strips 302 are or could be stent structures. Therefore, Hossainy *et al.* does not anticipate claimed subject matter, because claimed outer stents are not disclosed or inferred.[3]

In particular, the strips 302, from their very physical arrangements on stent 300 are precluded from in any way providing or suggesting an outer stent structure positioned on stent 300. The strips 302 are only interconneted via stent 300 structure. Therefore, only stent 300 can be a body lumen support device. Collectively, strips 302, without stent 300, are physically not capable of being a support device about the radial exterior of stent 300. Any

[3] "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)

vessel or cavity in which stent 300 would be positioned would only be supported from collapse by stent 300 and not strips 302. Here there only is one stent and that is stent 300.

Identically, in the case of Hossainy *et al.* disclosed combinations of stent 100 and bands 209 there only is one stent, i.e., support device, and that is stent 100. Bands 209 are explicitly disclosed as being "viscoelastic materials having a high creep compliance because such materials are easily expandable and typically exert a gradual and weak *restoring force* that avoids collapsing or substantially deforming an expanded stent over time." (Emphasis added, col. 3, lines 44-49) Nowhere do Hossainy *et al.* disclose or suggest that bands 209 "exert a radial force in an outward direction" as is stated in section 4 of the final action. Instead Hossainy *et al.* disclose, without contradiction, that bands 209 "typically exert a gradual and weak *restoring force* that avoids collapsing or substantially deforming an expanded stent over time." (Emphasis added) In context, the restoring force that bands 209 apply about stent 100 is without exception an inward directed force and does not include any radial force in an outward direction. Bands 209 are not disclosed or suggested as being any body lumen or vessel support device. These bands 209 in exerting restoring forces, i.e., collapsing forces, on stent 100 oppose application of radial outward forces with their inward directed forces.

> In one embodiment, the regioselective material forming bands 209 is applied to the stent 200 [sic] while the stent 200 [sic] is a compressed position. Because the stent 200 [sic] may later be expanded at a treatment site, it is important to choose a regioselective material that will expand as stent 200 [sic] expands without tearing and without exerting a harmful compressive restoring force. One way of ensuring proper stent expansion is to use a regioselective material having a high creep comliance and a modulus of elasticity lower than that of the structural material forming the main body of stent 200 [sic]. (Col. 3, lnes 20-29)

Bands 209 are not stents. Hossainy *et al.* only disclose a single stent and that is stent 100 with constricting bands 209.

The purpose for bands 209 disclosed by Hossainy *et al.* – other than providing a "weak restoring force" about stent 100 – is to provide a "regioselective material." That is a material that is capable of having selected compounds, such as drugs, incorporated with the material, e.g., see Col. 1, lines 6-9.

> [A] need exists for a composite stent providing a mechanism for increasing the dosages of drugs and radiation at the stent ends, and for a method providing a procedure for forming elastomeric bands or strips containing desired therapeutic agents *in situ* about the main body of a stent. (Col. 2, lines 11-16)

Specifically, Hossainy *et al.* disclose: "Anti-proliferative drugs, anti-platelet drugs, TB3A inhibitors, and nictric [sic] oxide donors, bioactive drugs, blood compatible matrices, and radioactive emitters may be incorporated in the structural and/or regioselective materials forming stent 200 [sic]." (Col. 3, lines 58-62) An exemplary list of "bioactive drugs that may be used to form a regioselective band 209..." is set out by Hossainy *et al.* at col. 4, lines 4-31. Hossainy *et al.*, therefore, disclose as the purpose for bands 209, the providing of a material about a stent that can incorporate selected compounds, drugs, etc. These selected compounds, drugs, etc. are to be introduced to a body lumen or vessel using bands 209.

The record is explicit, Hossainy *et al.* consistently call their disclosed structures 100, 200 and 300 stents. The Hossainy *et al.* bands 209 and strips 302 never are disclosed or suggested anywhere in their patent as being stents. As in this appealed application, Hossainy *et al.* disclose stents to be known specific medical procedure structures that are expanded and used to support vessels, orifaces and lumens in open configurations.

[A]rteriosclerosis is a medical condition that affects many patients. Fortunately, using medical procedures such as Percutaneous Transluminal Angioplasty (PTA), a sufficient flow of blood can be restored by implanting a tiny mesh tubular structure called a stent inside the affected lumen. In a typical PTA procedure, a stent is crimped about an inflatabale balloon attached to the distal end of a catheter.... The catheter's distal end is maneuvered to a site of stenosis, where the balloon is inflated to expand the stent, compress the stenosis, and widen the lumen. The catheter is withdrawn after deflating the balloon. (Col. 1, lines 12-24)

Stents may be of various types. Those that are crimped about a balloon and expanded by inflating the balloon are called balloon-expandable stents. Those that are crimped about a balloon and expanded by inflating the balloon with a warm or hot liquid are called thermal self-expanding stents. And, those that are compressed within a tubular sleeve and expanded by withdrawing the tubular sleeve are called self-expanding stents. (Col. 1, lines 44-51)

The Examiner in "maintain[ing] that the bands of Hossainy et al. can be characterized as outer stents" (Advisory Action) inserts his own judgment in contradiction to Hossainy *et al.* explicit and consistent disclosures that only their structures 100, 200 and 300 are stents. Their bands 209 nowhere are disclosed or suggested as being stents, but instead are disclosed as being regioselective materials that exert gradual weak restoring forces against expanded stents.

Hossainy *et al.* do not disclose or suggest combining any pair of stents to form a composite stent as covered in the rejected claims.

2. Hossainy *et al.* Does Not Disclose or Suggest a "Method of Treatment [for] Expanding [an] Inner Stent To Cause [an] Outer Stent To...Contact...[a] Body Lumen" as Required By Method Claims 29 and 33-35

As previously explained, there is only one stent included in the Hossainy *et al.* so-called disclosed composite stent structures. See section VII(c)(1). Accordingly, Hossainy *et al.* do not disclose or suggest a method for inserting and expanding any composite stent that includes an inner stent within an outer stent as required by method claims 29 and 33-35.

Furthermore, in not disclosing or suggesting any combination of an inner and outer stent to form a composite stent, Hossainy *et al.* fail to disclose or suggest a method for transporting a substance through such a composite stent structure as is covered in claim 29.

CONCLUSION

Accordingly, for all of the foregoing reasons, none of the appealed claims are anticipated by the asserted prior art. Therefore, the Examiner's rejections should be reversed.

Date: July 16, 2007

Respectfully submitted,

By _____

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VIII. CLAIMS APPENDIX

A copy of claims involved in this Appeal for Application Serial No. 09/963,676 are listed below.

Claim 2 (Previously Presented): The composite stent of claim 28 wherein said outer stent and said inner stent are deployed separately and attached *in-vivo*.

Claim 3 (Previously Presented): The composite stent of claim 28 wherein said inner and said outer stents are inserted within the body lumen as a unit.

Claim 7 (Previously Presented): The composite stent according to claim 28 wherein said inner stent is configured to provide a radially outward bias so as to position said outer stent into engagement with the body lumen.

Claim 23 (Previously Presented) A composite stent comprising:

a bioabsorbable stent; and

a self-expanding metal stent releasably engageable within said bioabsorbable stent for insertion within a body lumen as a unit, said self-expanding metal stent biased to position said bioabsorbable stent into engagement with the body lumen.

Claim 24 (Previously Presented) The stent according to claim 23 wherein said bioabsorbable stent comprises a bioabsorbable ploymer.

Claim 28 (Previously Presented) A composite stent comprising:

an outer stent, said outer stent being a bioabsorbable stent, and said outer stent being open at opposite ends and having an outer surface engageable with an inner surface of a body lumen; and

an inner stent, said inner stent being a self-expanding metal stent, and said inner stent being open at opposite ends, said inner stent engageable with said outer stent to form a composite structure insertable within the body lumen, said inner stent configured to assist said outer stent in retaining a position of the outer stent within the body lumen.

Claim 29 (Previously Presented) A method of treatment comprising the steps of:

inserting a composite stent structure into a body lumen, said composite stent structure including an inner stent being made of a self-expanding metal, said inner stent being within an outer stent said outer stent being made of a bioabsorbable material;

expanding said inner stent to cause said outer stent to be positioned into contact with an inner wall of the body lumen; and

allowing for normal functioning of the body lumen by transporting a bodily substance through said composite stent structure.

Claim 30 (Previously Presented) A composite stent comprising:

a first stent; and

a second stent engageable with said first stent to form a composite structure insertable within a body lumen, said second stent configured to assist said first stent in retaining a position of the first stent within the body lumen.

Claim 31 (Previously Presented) The composite stent of claim 30 wherein said first stent is a bioabsorbable stent.

Claim 32 (Previously Presented) The composite stent of claim 30 wherein said second stent is a self-expanding metal stent.

Claim 33 (Previously Presented) A method of treatment comprising the steps of:

inserting a composite stent structure into a body lumen, said composite stent structure including an inner stent being within an outer stent; and,

expanding said inner stent to cause said outer stent to be positioned into contact with an inner wall of the body lumen.

Claim 34 (Previously Presented) The method of claim 33 wherein said inner stent is a self-expanding metal stent.

Claim 35 (Previously Presented) The method of claim 33 wherein said outer stent is a bioabsorbable stent.

IX. EVIDENCE APPENDIX

There is no evidence pursuant to 37 C.F.R. §§ 1.130, 1.131 or 1.132 or entered by or relied upon by the Examiner to be submitted.

X. RELATED PROCEEDINGS APPENDIX

There are no related proceeding identifications or copies of decisions to be provided.